

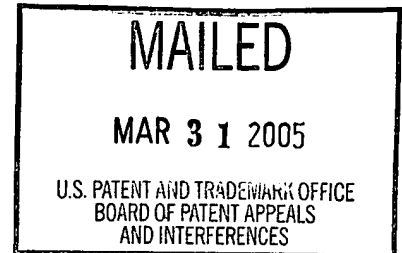
UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte Thomas B. Carlson

Appeal No. 2004-2317¹
Application No. 09/771,938

Heard: February 10, 2005²



Before SCHEINER, ADAMS and GREEN, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the
examiner's final rejection of claims 3, 6, 11, 14-20, 24, 25, and 27-31. The
examiner has indicated that claims 1, 2, 5, 7-10, 12, 13 and 21-23 are allowable.
Answer, page 2. Claims 4 and 26 are cancelled. Brief, page 2.

¹ This appeal is substantially similar to Appeal No. 2004-1503, Application No. 09/606,808;
Appeal No. 2004-1506, Application No. 09/771,938; Appeal No. 2004-1968, Application No.
10/00,0311; Appeal No. 2004-2343, Application No. 09/772,520; and Appeal No. 2005-0396,
Application No. 10/077,589, which all share the same assignee, Monsanto Company, the parent
of wholly-owned subsidiary DeKalb Genetics Corporation. Accordingly we have considered these
appeals together.

² We note that examiner Ashwin Meta presented arguments at the oral hearing.

Claims 3, 6, 15, 16, 17, 27, 28, 30 and 31 are illustrative of the subject matter on appeal and are reproduced below. In addition, for convenience, we have reproduced allowable claims 2 and 5 below:

2. A population of seed of the corn variety I015036, wherein a sample of the seed of the corn variety I015036 was deposited under ATCC Accession No. PTA-3225.
3. The population of seed of claim 2, further defined as an essentially homogeneous population of seed.
5. A corn plant produced by growing a seed of the corn variety I015036, wherein a sample of the seed of the corn variety I015036 was deposited under ATCC Accession No. PTA-3225.
6. The corn plant of claim 5, having:
 - (a) an SSR profile in accordance with the profile shown in Table 6; or
 - (b) an isozyme typing profile in accordance with the profile shown in Table 7.
15. A corn plant capable of expressing all the physiological and morphological characteristics of the corn variety I015036, wherein a sample of the seed of the corn variety I015036 was deposited under ATCC Accession No. PTA-3225.
16. The corn plant of claim 15, further comprising a nuclear or cytoplasmic gene conferring male sterility.
17. A tissue culture of regenerable cells of a plant of corn variety I015036, wherein the tissue is capable of regenerating plants capable of expressing all the physiological and morphological characteristics of the corn variety I015036, wherein a sample of the seed of the corn variety I015036 was deposited under ATCC Accession No. PTA-3225.
27. The corn plant of claim 5, further defined as having a genome comprising a single locus conversion.
28. The corn plant of claim 27, wherein the single locus was stably inserted into a corn genome by transformation.
30. The corn plant of claim 27, wherein the locus confers a trait selected from the group consisting of herbicide tolerance; insect resistance; resistance to bacterial, fungal, nematode or viral disease; yield enhancement; waxy

starch; improved nutritional quality; enhanced yield stability; male sterility and restoration of male fertility.

31. A method of producing an inbred corn plant derived from the corn variety I015036, the method comprising the steps of:

- (a) preparing a progeny plant derived from the corn variety I015036 by crossing a plant of the corn variety I015036 with a second corn plant, wherein a sample of the seed of the corn variety I015036 was deposited under ATCC Accession No. PTA-3225;
- (b) crossing the progeny plant with itself or a second plant to produce a seed of a progeny plant of a subsequent generation;
- (c) growing a progeny plant of a subsequent generation from said seed and crossing the progeny plant of a subsequent generation with itself or a second plant;
- (d) repeating steps (b) and (c) for an addition[al] 3-10 generations to produce an inbred corn plant derived from the corn variety I015036.

The references relied upon by the examiner are:

Hunsperger et al. (Hunsperger) 5,523,520 Jun. 4, 1996

Eshed et al. (Eshed), "Less-Than-Additive Epistatic Interactions of Quantitative Trait Loci in Tomato," Genetics, Vol. 143, pp. 1807-17 (1996)

Kraft et al. (Kraft), "Linkage Disequilibrium and Fingerprinting in Sugar Beet," Theoretical and Applied Genetics, Vol. 101, pp. 323-36 (2000)

GROUND OF REJECTION

Claim 3 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "an essentially homogeneous population of seed."

Claim 14 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "[a]n essentially homogeneous population of corn plants produced by growing the seed of the corn variety I015036."

Claims 6 and 11 stand rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "in accordance with."

Claims 15, and 17-20³ stand rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "capable of expressing."

Claims 16 and 27-30⁴ stand rejected under 35 U.S.C. § 112, second paragraph as failing to limit the scope of the claims from which they depend.

Claim 28 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of "the article 'a' in the recitation 'wherein the single locus was stably inserted into a corn genome.'"

Claim 30 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrases "yield enhancement," "improved nutritional quality," and "enhanced yield stability."

Claims 6, 11, 24, 25 and 27-31 stand rejected under the written description provision of 35 U.S.C. § 112, first paragraph.

Claims 27-30 stand rejected under the enablement provision of 35 U.S.C. § 112, first paragraph.

We reverse.

³ According to the examiner (Answer, page 13), since claim 18 depends from claims 17 it is included in this rejection. We also note, while the examiner lists (Answer, page 4) claim 19 as rejected under 35 U.S.C. § 112, second paragraph, the examiner fails to explain the basis of this rejection. Accordingly, we assume since claim 19 ultimately depends from claim 17, claim 19, like claim 18, was intended to be included in this rejection.

⁴ According to the examiner (Answer, page 4), "[c]laims ... 27-30 ... stand rejected under 35 U.S.C. [§] 112, second paragraph..." The examiner, however, provides no explanation as to why claim 29 is rejected. We can only assume that since claim 29, as well as claims 28 and 30, each depend from claim 27, they are rejected for the same reason as claim 27. Accordingly, we have included claims 28-30 with this ground of rejection.

BACKGROUND

The present "invention relates to inbred corn seed and plants of the variety designated I015036, and derivatives and tissue cultures thereof." Specification, page 1. According to appellant (specification, page 27), "[a] description of the physiological and morphological characteristics of corn plant I015036 is presented in Table 3" of the specification, pages 27-29. On this record the examiner has indicated that claims drawn to plants, plant parts, and seed of the corn variety designated I015036 are allowable. See e.g., claims 1, 2, 5, 7-10, 12 and 13, and Answer, page 2, wherein the examiner states "[c]laims 1, 2, 5, 7-10, 12 [and] 13 ... are allowed."

A second aspect of the present invention comprises hybrid plants and processes "for producing [first generation (F₁) hybrid⁵] corn seeds or plants, which ... generally comprise crossing a first parent corn plant with a second parent corn plant, wherein at least one of the first or second parent corn plants is a plant of the variety designated I015036." Specification, pages 7-9. On this record the examiner has indicated that claims drawn to a process of producing corn seed wherein the process comprises crossing a first parent corn plant with a second parent corn plant are allowable. See e.g., claims 21-23 and Answer, page 2, wherein the examiner states claims "21-23 are allowed."

⁵ According to the specification (page 21), a F₁ hybrid is "[t]he first generation progeny of the cross of two plants." During oral hearing, appellant confirmed that all claims drawn to hybrid plants or hybrid seeds (see e.g., claims 24 and 25) refer to F₁ hybrids.

A third aspect of the present invention comprises single locus converted plants of the corn variety I015036. Specification, page 6. As appellant explains (specification, page 23, emphasis added), single locus converted (conversion) plants are those plants

which are developed by a plant breeding technique called backcrossing wherein essentially all of the desired morphological and physiological characteristics of an inbred are recovered in addition to the characteristics conferred by the single locus transferred into the inbred via the backcrossing technique. A single locus may comprise one gene, or in the case of transgenic plants, one or more transgenes integrated into the host genome at a single site (locus).

As appellant explains (specification, page 31):

Many single locus traits have been identified that are not regularly selected for in the development of a new inbred but that can be improved by backcrossing techniques. Single locus traits may or may not be transgenic; examples of these traits include, but are not limited to, male sterility, waxy starch, herbicide resistance, resistance for bacterial, fungal, or viral disease, insect resistance, male fertility, enhanced nutritional quality, industrial usage, yield stability, and yield enhancement. These genes are generally inherited through the nucleus, but may be inherited through the cytoplasm. Some known exceptions to this are genes for male sterility, some of which are inherited cytoplasmically, but still act as single locus traits.

A final aspect of the present invention is directed to a process of producing an inbred corn plant derived from a plant of the corn variety I015036.

See e.g., claim 31. According to appellant's specification (bridging paragraph, pages 10-11),

the present invention provides a method of producing an inbred corn plant derived from the corn variety I015036, the method comprising the steps of: (a) preparing a progeny plant derived from corn variety I015036, wherein said preparing comprises crossing a plant of the corn variety I015036 with a second corn plant, and

wherein a sample of the seed of corn variety I015036 has been deposited under ATCC Accession No. ... [PTA-3225]; (b) crossing the progeny plant with itself or a second plant to produce a seed of a progeny plant of a subsequent generation; (c) growing a progeny plant of a subsequent generation from said seed of a progeny plant of a subsequent generation and crossing the progeny plant of a subsequent generation with itself or a second plant; and (d) repeating steps (c) and (d) for an addition 3-10 generations to produce an inbred corn plant derived from the corn variety I015036. In the method, it may be desirable to select particular plants resulting from step (c) for continued crossing according to steps (b) and (c). By selecting plants having one or more desirable traits, an inbred corn plant derived from the corn variety I015036 is obtained which possesses some of the desirable traits of corn variety I015036 as well potentially other selected traits.

According to the examiner (Answer, page 36), "[t]he patentability of the method of claim 31 does not lie in the method steps, which require the simple acts of crossing corn plants, allowing progeny seed to be produced, and growing progeny plants from the seed...." Therefore, as we understand this aspect of the claimed invention (e.g., claim 31), the intent is not to claim a specific inbred corn plant resulting from the claimed process. See claim 31. Instead, as we understand it, claim 31 is drawn to a process wherein an inbred corn plant is derived from the corn variety I015036.

As appellant explains (specification, page 3),

The development of uniform corn plant hybrids requires the development of homozygous inbred plants, the crossing of these inbred plants, and the evaluation of the crosses. Pedigree breeding and recurrent selection are examples of breeding methods used to develop inbred plants from breeding populations. Those breeding methods combine the genetic backgrounds from two or more inbred plants or various other broad-based sources into breeding pools from which new inbred plants are developed by selfing and selection of desired phenotypes. The new inbreds are crossed with other inbred plants and the hybrids from these crosses are evaluated to determine which of those have commercial potential.

We emphasize, that while “new inbreds” having commercial potential may result from the method set forth in claim 31, the claim does not encompass any specific plant that is produced as a result of the method. Rather the claim encompasses only a method of producing an inbred corn plant that is “derived” from the corn variety I015036. The examiner has indicated that a claim drawn to a corn plant of the corn variety I015036 is allowable. See e.g., claim 5, and Answer, page 2, wherein the examiner states that claim 5 is allowed.

Against this backdrop, we now consider the rejections of record.

DISCUSSION

Definiteness:

Claims 3, 6, 11, 14-20 and 27-30 stand rejected under 35 U.S.C. § 112, second paragraph. For the following reasons we reverse.

Claim 3

Claim 3 depends from independent claim 2, and stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase “an essentially homogeneous population of seed....” Answer, bridging paragraph, pages 4-5. According to the examiner (Answer, page 4), claim 2 is drawn to “[a] population of seed of the corn variety I015036, wherein a sample of the seed of the corn variety I015036 was deposited under ATCC Accession No. PTA-3225.” Thus, the examiner finds (Answer, page 5), the population of seed set forth in claim 2 “is a homogeneous population of seed of corn variety I015036.”

Accordingly, the examiner finds (id.), “[t]he recitation, ‘essentially homogeneous,’ in claim 3 ... appear[s] to be superfluous.”

However, as disclosed in appellant’s specification (page 5),

[e]ssentially homogeneous populations of inbred seed are those that consist essentially of the particular inbred seed, and are generally free from substantial numbers of other seed, so that the inbred seed forms between about 90% and about 100% of the total seed, and preferably, between about 95% and about 100% of the total seed.

Accordingly, we disagree with the examiner’s assertion (Answer, page 6) that claim 3 is unclear simply because it may contain seed other than the seed of the corn variety I015036. We remind the examiner that claim language must be analyzed “not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary skill in the pertinent art.” In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971). Here, notwithstanding appellant’s comments⁶, it is our opinion that a person of ordinary skill in the art would recognize that an essentially homogeneous population of seed of the corn variety I015036 is a population of seed that is generally free from substantial numbers of other seed, e.g., wherein corn variety I015036 seed forms between about 90% and about 100% of the total seed in the population.⁷

⁶ According to appellant (Brief, page 7), an essentially homogeneous population of seed, is a population of seed that could be of non-uniform size and shape.

⁷ Cf. the examiner’s statement (Answer, page 6), “amending claim 3 to read ‘[a]n essentially homogeneous population of corn seeds consisting essentially of seed of claim 1’, would obviate this rejection.”

Accordingly, we reverse the rejection of claim 3 under 35 U.S.C. § 112, second paragraph.

Claim 14

Claim 14 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase “[a]n essentially homogeneous population of corn plants produced by growing the seed of the corn variety I015036.” Answer, page 6. According to the examiner (Answer, bridging paragraph, pages 6-7), “[t]he I015036 seed can only produce I015036 plants. ... [Therefore,] [t]he population can ... only consist of I015036 plants.” Accordingly, the examiner finds it unclear “why the population is referred to as ‘essentially homogeneous,’ since such populations can comprise more than one variety of plant.” Answer, page 7.

As appellant discloses (specification, page 6), “[t]he population of inbred corn seed of the invention can further be particularly defined as being essentially free from hybrid seed. The inbred seed population may be separately grown to provide an essentially homogeneous population of inbred corn plants designated I015036.” As we understand the claim, growing the seed of claim 3, for example, would produce an essentially homogeneous population of corn plants of the corn variety I015036.⁸

⁸ Cf. The examiner’s statement (Answer, page 8), amending claim 14 “to read, ‘[a]n essentially homogeneous population of corn plants produced by growing a population of corn seed consisting essentially of the seed of corn plant I015036...’ would obviate the rejection.”

In addition, we direct the examiner's attention to Appeal No. 2005-0396, wherein a claim similar to claim 14 was presented for our review. In Appeal No. 2005-0396, the examiner of record indicated that claim 14, directed to "[a]n essentially homogeneous population of corn plants produced by growing the seed of the corn variety I180580...." was allowable. Accordingly, we find that the examiner has treated claim 14 in a manner that is inconsistent with the prosecution of claim 14 in 2005-0396. As we understand it, the only difference between claim 14 as it appears in Appeal No. 2005-0396 and the instant appeal is the variety of corn seed from which the plant is produced.

Accordingly we reverse the rejection of claim 14 under 35 U.S.C. § 112, second paragraph.

Claims 6 and 11

Claims 6 and 11 stand rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "in accordance with." According to the examiner (Answer, page 9), it is unclear if a plant "that generally follows the trend of the profile of Table 6, but which differs at one or a few loci, [would] be considered in 'conformity' or 'in accordance' with the profile of Table 6."

On this record, we understand the phrase "in accordance with" as it is used in claims 6 and 11 to mean "the same"⁹. Stated differently, we understand the claims to read:

6. The corn plant of claim 5, having:
 - (a) the same SSR profile as shown in Table 6; or

⁹ During the February 10, 2005 oral hearing appellant's representative confirmed that the phrase "in accordance with" was intended to mean "the same."

(b) the same isozyme typing profile as shown in Table 7.

11. The plant part of claim 10, wherein said cell is further defined as having:
- (a) The same SSR profile as shown in Table 6; or
 - (b) The same isozyme typing profile as shown in Table 7.

Accordingly we reverse the rejection of claims 6 and 11 under 35 U.S.C. § 112, second paragraph.

Claims 15 and 17-20

Claims 15, and 17-20 stand rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase “capable of expressing,” or “capable of regenerating.” According to the examiner (Answer, page 11), the claims do “not make clear if the plant actually expresses the traits, or when or under what conditions the traits are expressed.” In this regard, the examiner finds (Answer, page 12),

while the plant has the capacity to express the characteristics, for some reason it may not. Certain characteristics of a plant are expressed only at certain times of its life cycle, and are incapable of being expressed at other times. The colors of flower parts such as silks, or fruit parts such as husks, are examples. The promoters of many genes conferring traits require a transcription factor to become active. Is a plant that has such a gene, but not the transcription factor, considered “capable of expressing” that gene, and the trait associated with that gene, and is such a plant encompassed by the claims?

To address the examiner’s concerns, we find it sufficient to state that if a plant has the capacity to express the claimed characteristics it meets the requirement of the claim regarding “capable of,” notwithstanding that due to a particular phase of the life cycle the plant is not currently expressing a particular characteristic. Alternatively, if a plant is incapable of expressing the claimed

characteristics at any phase of the life cycle, because it lacks, for example, the “transcription factor” required for expression – such a plant would not meet the requirement of the claim regarding “capable of.”

Here, we find the examiner's extremely technical criticism to be a departure from the legally correct standard of considering the claimed invention from the perspective of one possessing ordinary skill in the art.¹⁰ In our opinion, a person of ordinary skill in the art would understand what is claimed. Amgen Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir. 1991). We find the same to be true for the phrase “capable of” as set forth in claims 17-20.

Accordingly we reverse the rejection of claims 15, and 17-20 under 35 U.S.C. § 112, second paragraph.

Claims 16 and 27-30

Claims 16 and 27-30 stand rejected under 35 U.S.C. § 112, second paragraph as failing to limit the scope of the claims from which they depend. According to the examiner (Answer, page 9), since the plant set forth in claim 16 is male sterile it cannot express all the morphological and physiological characteristics of the male fertile corn variety I015036. Similarly, the examiner finds it unclear whether the plant set forth in claim 27 has all the characteristics of the plant set forth in claim 5, from which claim 27 depends. Id. In response,

¹⁰ Cf. Digital Equipment Corp. v. Diamond, 653 F.2d 701, 724, 210 USPQ 521, 546 (CA 1981).

appellant asserts (Brief, bridging paragraph, pages 8-9), claims 16 and 27 simply add a further limitation to the claims from which they depend. We agree.

For example, claim 16 reads on a corn plant capable of expressing all the physiological and morphological characteristics of the corn variety I015036, further comprising a nuclear or cytoplasmic gene conferring male sterility. In our opinion, the claims reasonably apprise those of skill in the art of their scope.

Amgen, As set forth in Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 758 F.2d 613, 624, 225 USPQ 634, 641 (Fed. Cir. 1985), “[i]f the claims, read in the light of the specifications, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more.”

Accordingly we reverse the rejection of claims 16 and 27-30 under 35 U.S.C. § 112, second paragraph.

Claim 28

Claim 28 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of “the article ‘a’ in the recitation ‘wherein the single locus was stably inserted into a corn genome.’” According to the examiner (Answer, page 13), “[t]he recitation does not make clear if the genome is that of I015036 or that of a different corn plant.”

According to appellant’s specification (page 23, emphasis removed), a “Single Locus Converted (Conversion) Plant” refers to

[p]lants which are developed by a plant breeding technique called backcrossing wherein essentially all of the desired morphological and physiological characteristics of an inbred are recovered in

addition to the characteristics conferred by the single locus transferred into the inbred via the backcrossing technique. A single locus may comprise one gene, or in the case of transgenic plants, one or more transgenes integrated into the host genome at a single site (locus).

Accordingly, we agree with appellant (Brief, page 10) “[t]he single locus referred to in claim 28 may or may not have been directly inserted into the genome of the claimed plant.” As we understand the claim, and arguments of record, claim 28 presents two possibilities: (1) the single locus is directly inserted into the claimed plant and nothing further need be done; or (2) the single locus is directly inserted into a different plant, which is then used to transfer the single locus to the claimed plant through use of the plant breeding technique known as backcrossing.

In our opinion, the claim reasonably apprises those of skill in the art of its scope. Amgen. Accordingly, we reverse the rejection of claim 28 under 35 U.S.C. § 112, second paragraph.

Claim 30

Claim 30 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrases “yield enhancement,” “improved nutritional quality,” and “enhanced yield stability.” According to the examiner the terms “yield enhancement,” “improved nutritional quality,” and “enhanced yield stability” are relative and have no definite meaning. Answer, page 14. The examiner is correct (Answer, page 14), when a word of degree is used appellant’s specification must provide some standard for measuring that degree.

Seattle Box. Co. v. Industrial Crating & Packing, Inc., 731 F.2d 818, 826, 221 USPQ 568, 573-574 (Fed. Cir. 1984).

On this record, appellant asserts (Brief, page 11), it is “understood the enhancement of yield or yield stability and improved nutritional quality is relative to a plant lacking the single locus. The metes and bounds of the claim are thus fully understood by one of skill in the art and the use of the terms is not indefinite.” On reflection, we agree with appellant. The fact that some claim language is not mathematically precise does not per se render the claim indefinite. Seattle Box. As set forth in Shatterproof Glass, “[i]f the claims, read in the light of the specifications, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more.” In our opinion, a person of ordinary skill in the art would have understood the enhancement of yield or yield stability and improved nutritional quality is relative to a plant lacking the single locus.

Accordingly we reverse the rejection of claim 30 under 35 U.S.C. § 112, second paragraph.

Written Description:

Claims 6, 11, 24, 25 and 27-31 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification fails to adequately describe the claimed invention. For the following reasons, we reverse.

Claims 24 and 25¹¹

Claims 24 and 25 both depend from claim 23. On this record, the examiner has indicated that claim 23 is allowable. Answer, page 2. The examiner finds (Answer, page 16), claims 24 and 25 are drawn to a hybrid plant or seed “produced by crossing inbred corn plant I015036 with any second, distinct inbred corn plant.”

As we understand it, based on this construction of claims 24 and 25, the examiner is of the opinion that since the hybrids inherit only $\frac{1}{2}$ of their diploid¹² set of chromosomes from the plant of corn variety I015036, a person of skill in the art would not have viewed the teachings of the specification as sufficient to demonstrate that appellant was in possession of the genus of hybrid seeds and plants encompassed by claims 24 and 25. According to the examiner (Answer, page 22), “[t]he fact that any hybrid plant will inherit half of its alleles from I015036 then does not provide sufficient description of the morphological and physiological characteristics expressed by the claimed hybrid plants.”

There is no doubt that the expressed gene products of a hybrid plant, e.g., the morphological and physiological traits, of I015036 and a non-I015036 corn plant will depend on the combination of the genetic material inherited from both parents. See Answer, page 23. Nevertheless, we disagree with the examiner’s

¹¹ We recognize, as does the examiner (Answer, page 22) that appellant’s reference to claims 22-26 (Brief, page 13) was intended to be a reference to claims 24 and 25.

¹² According to appellant’s specification (page 21), diploid means “a cell or organism having two sets of chromosomes.”

conclusion (id.) that “[t]he fact that any hybrid plant will inherit half of its alleles from I015036 then does not provide sufficient description of the morphological and physiological characteristics expressed by the claimed hybrid plants.”

On these facts, we find it necessary to take a step back and consider what is claimed. The claims are drawn to a F₁ hybrid seed (claim 24) or plant (claim 25) resulting from a cross between a plant of corn variety I015036 and a non-I015036 corn variety. The claims do not require the hybrid to express any particular morphological or physiological characteristic. Nor do the claims require that a particular non-I015036 corn variety be used.¹³ All that is required by the claims is that the hybrid has one parent that is a plant of corn variety I015036. Since the examiner has indicated that the seed and the plant of the corn variety I015036 are allowable (see claims 1 and 5), there can be no doubt that the specification provides an adequate written description of this corn variety. In addition, the examiner appears to recognize (Answer, page 25) that appellant’s specification describes an exemplary hybrid wherein one parent was a plant of the corn variety I015036, see e.g., specification, pages 53-59. Accordingly, it is unclear to this merits panel what additional description is necessary.

As set forth in Reiffin v. Microsoft Corp., 214 F.3d 1342, 1345, 54 USPQ2d 1915, 1917 (Fed. Cir. 2000), the purpose of the written description

¹³ According to appellant (Brief, page 15), “hundreds or even thousands of different inbred corn lines were well known to those of skill in the art prior to the filing [date] of the instant application, each of which could be crossed to make a hybrid plant with in the scope of the claims.”

requirement is to “ensure that the scope of the right to exclude, as set forth in the claims does not overreach the scope of the inventor’s contribution to the field of art as described in the patent specification.” Here the hybrid seed or plant has one parent that is a plant of the corn variety I015036. To that end, to satisfy the written description requirement, the inventor “must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention” [emphasis added]. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). For the foregoing reasons it is our opinion that appellant has provided an adequate written description of the subject matter set forth in claims 24 and 25.

We recognize the examiner’s argument relating to SSR and isozyme markers (Answer, pages 25-29), as well as the examiner’s arguments concerning a correlation between the hybrid’s genome structure and the function of the hybrid plant (Answer, pages 23-25). However, for the foregoing reasons, we are not persuaded by these arguments.

Claims 6 and 11

Claims 6 and 11 depend ultimately upon claim 5. On this record, the examiner has indicated that claim 5 is allowable. Answer, page 2.

According to the examiner (Answer, page 8), while the specification provides the locus names and allele numbers of the SSR markers, the specification does not provide the actual nucleotide sequences that make up the markers. According to the examiner (Answer, page 18), “names of loci alone do not describe the structures of the markers themselves. Without a description of

the sequences of the markers, one cannot confirm their presence.” In response, appellant points out (Brief, page 26), “the SSR markers were from Celera AgGen, Inc., which provides a commercial service for genotyping of maize varieties.” In other words, a person of ordinary skill in the art could use the commercially available service provided by Celera AgGen, Inc. to determine whether a corn plant produced by growing a seed of the corn variety I015036 has an SSR profile which is the same as that shown in Table 6. Therefore, it is unclear to this panel why the examiner believes that such a disclosure fails to provide adequate written descriptive support for the claimed invention.¹⁴ Accordingly, we are not persuaded by the examiner’s argument.

Regarding the isozyme typing profile, the examiner finds (Answer, page 18), “Table 7 provides names of loci where isozyme markers reside, for three different corn plants, and a numerical value that represents the numbers of alleles at isozyme loci types. The nucleotide sequences that make up these loci are not described.” In response, appellant points out (Brief, page 26), the isozyme “markers are well known and isozyme analysis in general [is] very well known having been used for decades.” In this regard, we remind the examiner that the inquiry into whether the description requirement is met must be determined on a case-by-case basis and is a question of fact. In re Wertheim, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). A description as filed is

¹⁴ We are not persuaded by the examiner’s assertion (Answer, page 28) “that the [commercially available] service used to detect SSR markers is currently available is not a guarantee that it will remain so for the life of a patent issuing from the application.” Cf. In re Metcalfe, 410 F.2d 1378, 1382, 161 USPQ 789, 792-3 (CCPA 1969).

presumed to be adequate; unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See e.g., In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971).

The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. Accordingly, it is the examiner who has the initial burden of establishing by a preponderance of evidence that a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. Wertheim, 541 F.2d at 263, 191 USPQ at 97. On this record, the examiner provides no evidence to support the assertion that simply because appellant has not provided the sequences that make up the loci for particular isozymes, appellant's specification does not adequately describe the claimed invention. Accordingly, we are not persuaded by the examiner's argument.

The examiner finds (Answer, page 37), claims 6 and 11 require that the claimed plant or plant cell exhibit either the claimed SSR profile or the isozyme profile. According to the examiner (id.), "[t]he genome of the cells of the I015036 seed deposited with the ATCC has both the SSR profile and the isozyme typing profile shown in Tables 5 and 6 for that plant. No plant is mentioned in the specification that has one genetic marker profile but not the other." The examiner's concern appears to be misplaced. To the extent that the examiner is concerned that the claim is open to read on a plant other than a corn plant produced by growing a seed of the corn variety I015036, we remind the

examiner that both claims 6 and 11 ultimately depend from claim 5¹⁵, which is drawn to “[a] corn plant produced by growing a seed of the corn variety I015036....”

It appears that the examiner may have read claims 6 and 11 as drawn to a corn plant or plant cell having only one of the recited profiles. However, as we understand claims 6 and 11, determining whether the claimed corn plant (claim 6) or plant cell (claim 11) has one of the profiles does not mean that the plant, or plant cell would not also exhibit the other profile.

In addition, we direct the examiner’s attention to claims 6 and 11 of Appeal No. 2005-0396. As we understand it, notwithstanding differences in the SSR and isozyme profiles, the disclosure in the specification as well as the language of the claims is substantially similar to that of the instant application. Nevertheless, the examiner in Appeal No. 2005-0396 apparently found that appellant’s specification provided an adequate written description of the claimed invention as no rejection of claims 6 and 11 was made under the written description provision of 35 U.S.C. § 112, first paragraph in Appeal No. 2005-0396. Accordingly, we find that the examiner has treated claims 6 and 11 in a manner that is inconsistent with the prosecution of similar claims in related application 10/077,589, which is the subject matter of Appeal No. 2005-0396.

For the foregoing reasons, we are not persuaded by the examiner’s arguments.

¹⁵ The examiner has indicated that claim 5 is allowable. Answer, page 2.

Claims 27-30

According to the examiner (Answer, page 18), “[c]laims 27-30 are drawn towards I015036 plants further comprising a single locus conversion, or wherein the single locus was stably inserted into a corn genome by transformation.” The examiner finds, however, that “the specification does not describe identified or isolated single loci for all corn plant traits.” Answer, page 19. More specifically, the examiner finds (id.), claims 27-30 “broadly encompass single loci that have not been discovered or isolated.” To the extent that the examiner is asserting that appellant has not provided an enabling disclosure of single loci that have not been identified, we note that to satisfy the written description requirement, the inventor “must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention” [emphasis added]. Vas-Cath.

Nevertheless, it may be that the examiner’s concern (Answer, page 31), is that “single loci that alone govern ‘yield enhancement’ or ‘enhanced yield stability’ have not been discovered.” In this regard, the examiner asserts (Answer, page 32), “the references cited in the specification do not describe isolated single genes or loci that confer yield enhancement or yield stability.” Therefore, the examiner concludes (id.), “[a]ppellant cannot be in possession of plants further comprising single loci that have yet to be identified.” The examiner, however, provides no evidence to support the assertion that a person of ordinary skill in the art would not recognize that single loci for yield enhancement or yield stability are known in the art. In this regard, we note that

appellant discloses (specification, page 31), “[m]any single locus traits have been identified ... examples of these traits include, but are not limited to, ... enhanced nutritional quality, industrial usage, yield stability, and yield enhancement.” It appears that the examiner has overlooked appellant’s assertion that single locus traits for yield stability and yield enhancement are well known in the art. To this end, we direct the examiner’s attention to, for example, United States Patent No. 5,936,145 (‘145)¹⁶, issued August 10, 1999, which is prior to the filing date of the instant application. For clarity, we reproduce claims 8, 29 and 39 of the ‘145 patent below:

8. A corn plant having all the physiological and morphological characteristics of corn plant 87DIA4, a sample of the seed of said corn plant having been deposited under ATCC Accession No. 203192.
29. The corn plant of claim 8, further comprising a single gene conversion.
39. The single gene conversion of the corn plant of claim 29, where the gene confers enhanced yield stability.

As we understand it, claim 39 of the ‘145 patent, is drawn to a corn plant which comprises a single gene conversion, wherein the gene confers enhanced yield stability. Thus, contrary to the examiner’s assertion it appears, for example, that a single gene that confers enhanced yield stability was known in the art prior to the filing date of the instant application. We remind the examiner “a patent need not teach, and preferably omits, what is well known in the art.” Hybritech

¹⁶ We note that the assignee of the ‘145 patent is DeKalb Genetics Corporation. The assignee of the present application is Monsanto Company, the parent of wholly-owned subsidiary DeKalb Genetics Corporation.

Incorporated v. Monoclonal Antibodies, Inc. 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986).

We remind the examiner that the inquiry into whether the description requirement is met must be determined on a case-by-case basis and is a question of fact. Wertheim, 541 F.2d at 262, 191 USPQ at 96. A description as filed is presumed to be adequate; unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See e.g., Marzocchi. The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. Accordingly, it is the examiner who has the initial burden of establishing by a preponderance of evidence that a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. Wertheim, 541 F.2d at 263, 191 USPQ at 97. On this record, the examiner provides no evidence to support the assertion that single loci that govern, for example, yield enhancement or enhanced yield stability are not described.

For the foregoing reasons, we are not persuaded by the examiner's arguments.

Claim 31

Claim 31 is drawn to a method of producing an inbred corn plant derived from the corn variety I015036. The claimed method begins by crossing a plant of the corn variety I015036 with any other corn plant. The method requires that the progeny corn plant be crossed either to itself, or with any other corn plant, and that the progeny of this cross be further crossed to itself, or with another corn

plant, and so on throughout several generations. As we understand it, claim 31, in its simplest form, is directed to a method of using a plant of the corn variety I015036 to produce an inbred corn plant.

Nevertheless, the examiner finds (Answer, page 20), “[a] review of the claim indicates that hybrid progeny of corn plant I015036 are required to perform further crosses, and that progeny of subsequent generations can be further outcrossed with different corn plants.” Therefore, the examiner concludes (id.), “[t]he hybrid progeny of corn plant I015036, and progeny plants of subsequent generations, are essential to operate the claimed method.” As we understand the examiner’s argument, not only does appellant have to provide a written description of the starting corn plant (I015036), but appellant also must look into the future to determine every other potential corn plant that someone may wish to cross with the I015036 corn variety, and provide written descriptive support for not only every other corn plant that could be crossed with I015036, but also the resulting progeny of each cross.

As set forth in Reiffin, the purpose of the written description requirement is to “ensure that the scope of the right to exclude, as set forth in the claims does not overreach the scope of the inventor’s contribution to the field of art as described in the patent specification.” Here the method of producing an inbred corn plant requires a plant of the corn variety I015036 be used as the starting material. To that end, to satisfy the written description requirement, the inventor “must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention” [emphasis added].

Vas-Cath. The examiner has indicated that a claim to a plant of the corn variety I015036 is allowable, see e.g., appellant's claim 5. Therefore, in our opinion, there can be no doubt that appellant was in possession of a plant of the corn variety I015036, in addition to a method of using that plant to cross with any other corn plant to produce an inbred corn plant as set forth in appellant's claim 31.

In our opinion, it matters not what the other corn plants are, or what the progeny of a cross between corn variety I015036 and some other corn plant represents. As the examiner explains (Answer, bridging paragraph, pages 20-21), patentability of the method of claim 31 "does not lie in the method steps, which require the simple acts of crossing corn plants, allowing progeny seed to be produced, and growing progeny plants from the seed...." In our opinion, patentability of the method of claim 31 does not lie in the various other or second corn plants either. In our opinion, patentability of the method of claim 31 lies in the use of the corn variety I015036. Accordingly, for the foregoing reasons, it is our opinion that appellant has "convey[ed] with reasonable clarity to those skilled in the art that, as of the filing date sought, [they were] in possession of the invention," Vas-Cath (emphasis omitted).

Summary

For the foregoing reasons, we reverse the rejection of claims 6, 11, 24, 25 and 27-31 under the written description provision of 35 U.S.C. § 112, first paragraph.

Enablement:

Claims 27-30 stand rejected under the enablement provision of 35 U.S.C. § 112, first paragraph. The examiner finds (Answer, page 39), claims 27-30 “are broadly drawn towards inbred corn plant I015036 further defined as having a genome comprising any single locus conversion, encoding any trait; or wherein the single locus was stably inserted into a corn genome by transformation.” The examiner presents several lines of argument under this heading. We take each in turn.

I. Retaining all the morphological and physiological traits of I015036:

According to the examiner (Answer, page 38, emphasis added), “the specification does not teach any I015036 plants comprising a single locus conversion produced by backcrossing, wherein the resultant plant retains all of its morphological and physiological traits in addition to exhibiting the single trait conferred by the introduced single locus.” With reference to Hunsperger, Kraft, and Eshed the examiner asserts (Answer, page 41), “[t]he rejection raises the issue of how linkage drag hampers the insertion of single genes alone into a plant by backcrossing, while recovering all of the original plant’s genome.”

We note, however, that claims 27-30 do not require that the single locus conversion plant retain all of the morphological and physiological traits of the parent plant in addition to exhibiting the single trait conferred by the introduction of the single loci. Nor do claims 27-30 require that the resultant plant retain all of the original plant’s genome in addition to the single locus transferred into the

inbred via the backcrossing technique. As appellant explains (specification, bridging paragraph, pages 29-30, emphasis added),

[t]he term single locus converted plant as used herein refers to those corn plants which are developed by a plant breeding technique called backcrossing wherein essentially all of the desired morphological and physiological characteristics of an inbred are recovered in addition to the single locus transferred into the inbred via the backcrossing technique.

See also appellant's definition of single locus converted (conversion) plant at page 23 of the specification. We find nothing in the appellant's specification to indicate that the single locus converted plant retains all of the morphological and physiological traits, or all of the genome, of the parent plant in addition to the single locus transferred via the backcrossing technique. Accordingly, we disagree with the examiner's construction of claims 27-30 as "directed to exactly plant I015036, further comprising the single locus," which appears to disregard appellant's definition of a single locus converted plant. See Answer, page 43, emphasis added.

The examiner appears to appreciate (Answer, page 43) that appellant's specification provides an example of a converted plant. See e.g., specification, pages 35-36. However, for the foregoing reasons, we are not persuaded by the examiner's assertion (Answer, page 43) that the specification provides "no indication that all of the morphological and physiological traits of [this converted] ... corn plant were recovered, and that only one single locus was transferred from the donor plant." To the contrary, the examiner provides no evidence that the converted plant exemplified in appellant's specification did not retain

essentially all of the desired morphological and physiological characteristics of the inbred in addition to the characteristics conferred by the single locus transferred into the inbred via the backcrossing technique.

Further, we recognize appellant's argument (Brief, page 27) that the examiner failed to establish a nexus between Hunsperger's discussion of petunias; Kraft's discussion of sugar beets; and Eshed's discussion of tomatoes, and the subject matter of the instant application - corn. Absent evidence to the contrary, we agree with appellant (id.), the examiner's opinion¹⁷ that the references concerning petunias, sugar beets and tomatoes apply to corn is unsupported on this record. That the examiner has failed to identify (Answer, page 41) an example "in the prior art of plants in which linkage drag does not occur," does not mean that linkage drag is expected to occur in corn breeding, which according to appellant (Reply Brief, page 10) "is extremely advanced and well known in the art...." In this regard, we agree with appellant (Brief, page 28; Accord Reply Brief, page 11), the examiner has improperly placed the burden on appellant to demonstrate that the examiner's unsupported assertion is not true. We remind the examiner, as set forth in In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993):

When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for

¹⁷ See Answer page 41, wherein the examiner asserts "[l]inkage drag appears to be a phenomenon that occurs in all plant types."

doubting any assertions in the specification as to the scope of enablement.

II. What plant is transformed in claim 28?

We recognize the examiner's assertion (Answer, page 39) that while claim 28 requires that a single locus be stably inserted into a corn genome by transformation, the claim does not indicate whether (1) the I015036 plant was transformed with the single locus, or (2) some other corn plant was transformed with the single locus and then introduced into I015036 by crossing. However, as appellant points out (Brief, page 12), claim 28 "specifies that the single locus was stably inserted into a corn genome. Loci that are stably inserted into a corn genome are also stably inherited. Thus the single locus need not have been inserted into the genome of corn variety I015036." Accordingly, the I015036 plant may be transformed with the single locus, or another plant may be transformed with the single locus and then introduced into I015036 by crossing.

It may be that the examiner is concerned that by transforming a non-I015036 plant with a single locus and then introducing this locus into I015036 by crossing would result in a plant that does not retain all of the morphological and physiological traits, or all of the genome, of the I015036 plant. For the foregoing reasons, however, this line of reasoning is not persuasive.

III. The single locus to be introduced:

The examiner finds (Answer, page 40), "the claims do not place any limit on the single locus to be introduced" into I015036 plants. The examiner recognizes, however, that "[t]he prior art shows that hundreds of nucleotide

sequences encoding products that confer various types of plant traits have been isolated at the time the instant invention was filed.” Id. In addition, the examiner recognizes (id.), “[o]ne skilled in the art can transform any of these isolated nucleotide sequences known in the prior art into a corn plant cell, and regenerate a transgenic plant from the transformed cell.”

Nevertheless, the examiner finds (id.), “[u]ndue experimentation would be required by one skilled in the art to isolate single loci that govern the traits encompassed by the claims.” In this regard, the examiner asserts (Answer, page 44) that the claims broadly encompass corn plants comprising any type of single loci, including those that have not yet been identified or isolated. To the extent that the examiner is asserting that appellant has not provided an enabling disclosure of single loci that have not been identified, we note that enablement under 35 U.S.C. § 112, first paragraph is evaluated as of appellant’s filing date. As set forth in Chiron Corp. v. Genentech Inc., 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1325-26 (Fed. Cir. 2004), “a patent document cannot enable technology that arises after the date of application. The law does not expect an applicant to disclose knowledge invented or developed after the filing date. Such disclosure would be impossible. See In re Hogan, 559 F.2d 595, 605-06 [194 USPQ 527] (CCPA 1977).”

The examiner’s comment, however, may be directed to his assertion (Answer, page 40) that “isolated loci whose products confer yield enhancement or enhanced yield stability (recited in claim 30), are not known in the prior art.” However, as discussed, supra, it appears that contrary to the examiner’s

assertion a single locus that confers the trait of, for example, yield enhancement was known in the art prior to the filing date of the instant invention. In addition, as discussed, supra, appellant's specification asserts that such traits were known in the art. See specification, page 31. Accordingly, as set forth in In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971), the burden is on

the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure.

On this record, we find only the examiner's unsupported conclusions as to why the specification does not enable the claimed invention. We remind the examiner that nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples. Marzocchi, 439 F.2d at 223, 169 USPQ at 369. In the absence of an evidentiary basis to support the rejection, the examiner has not sustained his initial burden of establishing a prima facie case of non-enablement. In this regard, we note that the burden of proof does not shift to appellant until the examiner first meets his burden. Marzocchi, 439 F.2d at 223-224, 169 USPQ at 369-370.

We also recognize the examiner's assertion (Answer, pages 40-41) that claims 27-29 "encompass plants with single loci whose functions are unknown," or where the effects of expression of the single locus on the traits expressed by

I015036 are unknown. While this may be true, the examiner has not provided any evidence to suggest that it would require undue experimentation to obtain a single locus converted plant wherein essentially all of the desired morphological and physiological characteristics of an inbred are recovered in addition to the characteristics conferred by the single locus transferred into the inbred via the backcrossing technique. See specification, page 23.

While it is not expressly stated in the text of the examiner's rejection, it may be that the examiner is concerned that the claims include inoperative embodiments. If so, the examiner is directed to Atlas Powder Co. v. E.I. DuPont De Nemours & Co., 750 F.2d 1569, 1576-77, 224 USPQ 409, 414 (Fed. Cir. 1984):

Even if some of the claimed combinations were inoperative, the claims are not necessarily invalid. "It is not a function of the claims to specifically exclude ... possible inoperative substances...." In re Dinh-Nguyen, 492 F.2d 856, 859-59, 181 USPQ 46, 48 (CCPA 1974)(emphasis omitted). Accord, In re Geerdes, 491 F.2d 1260, 1265, 180 USPQ 789, 793 (CCPA 1974); In re Anderson, 471 F.2d 1237, 1242, 176 USPQ 331, 334-35 (CCPA 1971). Of course, if the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid. See e.g., In re Cook, 439 F.2d 730, 735, 169 USPQ 298, 302 (CCPA 1971).

On this record, the examiner provides no evidence that the number of inoperative embodiments is so large that a person of ordinary skill in the art would have to experiment unduly to practice the claimed invention. To the contrary, the examiner recognizes (Answer, page 40) that "[t]he prior art shows that hundreds of nucleotide sequences encoding products that confer various

types of plant traits have been isolated at the time the instant invention was filed"; and that "[o]ne skilled in the art can transform any of these isolated nucleotide sequences known in the prior art into a corn plant cell, and regenerate a transgenic plant from the transformed cell." Accordingly, we are not persuaded by the examiner's unsupported assertions.

For the foregoing reasons, we reverse the rejection of claims 27-30 under the enablement provision of 35 U.S.C. § 112, first paragraph.


SUMMARY

We reverse the rejection of claims 3, 6, 11, 14-20, and 27-30 under 35 U.S.C. § 112, second paragraph.

We reverse the rejection of claims 6, 11, 24, 25 and 27-31 under the written description provision of 35 U.S.C. § 112, first paragraph.

We reverse the rejection of claims 27-30 under the enablement provision of 35 U.S.C. § 112, first paragraph.

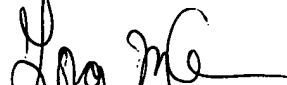
REVERSED



Toni R. Scheiner
Administrative Patent Judge



Donald E. Adams
Administrative Patent Judge



Lora M. Green
Administrative Patent Judge

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